DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Veregen
U.S. Patent No. 5,295,911
Docket No.: 2007E-0176
U.S. Patent No. 5,968,973
Docket No.: 2007E-0144

MAY 6 2008

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,295,911 and 5,968,973, filed by Mitsui Norin Co., Ltd., and Cancer Institute (Hospital), Chinese Academy of Medical Sciences, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Veregen (kunecatechins), the human drug product claimed by the patents.

The total length of the regulatory review period for Veregen (kunecatechins) is 3,002 days. Of this time, 2,605 days occurred during the testing phase and 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 14, 1998.

   The applicant claims August 13, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 14, 1998, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 30, 2005.

   The applicant claims September 23, 2005, as the date the new drug application (NDA) for Veregen (NDA 21-902) was initially submitted. However, FDA records indicate that NDA 21-902 was submitted on September 30, 2005.

3. The date the application was approved: October 31, 2006.

FDA has verified the applicant's claim that NDA 21-902 was approved on October 31, 2006.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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